

## Remarks

### **I. The Status of the Claims**

Claims 1-8, and 32 and 36, 38 and 39 are pending in the application. Claims 17-23, 34 and 37 are cancelled. Claims 38 and 39 are added. Applicants greatly appreciate the indication that claims 1-7, 32 and 36 are allowed. Claims 8, 17-23, 34 and 37 stand rejected.

### **II. The Rejection Under 35 U.S.C. § 103**

The Office Action rejects claims 17-23, 34 and 37 under 35 U.S.C. § 103 as being obvious over Jain et al. (US20020012675) in view of Banker et al., Chapter 11 in The Theory and Practice of Industrial Pharmacy, 1986, pp. 293-345; J.C. Carter Pharmaceutical Canada 2001, 1(3); Yamamoto et al. (U.S. Patent No. 5,756,123) and Sangekar et al. (U.S. Patent No. 4,992,277).

In response, to expedite prosecution of this application, Applicants cancel claims 17-23, 34 and 37 without prejudice or disclaimer as to the subject matter contained in claims 17-23, 34 and 37.

Applicants reserve the right to file continuation application(s) containing claims 17-23, 34 and 37. Reconsideration and withdrawal of the rejection of claims 17-23, 34 and 37 under 35 U.S.C. § 103 are respectfully requested.

### **III. The Rejection Under 35 U.S.C. § 112**

Claims 8 and 23 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for use of the term "substantially" with regard to the dosage form being "substantially" free of pores.

In response, the cancellation of claim 23 obviates any basis for the rejection of claim 23. With regard to claim 8, the specification defines the meaning of substantially free of pores as follows:

[0086] In embodiments in which the composition is prepared by molding, the composition typically is **preferably substantially free of pores in the diameter range of 0.5 to 5.0 microns, i.e. has a pore volume in the pore diameter range of 0.5 to 5.0 microns of less than about 0.02 cc/g, preferably less than about 0.01 cc/g, more preferably less than about 0.005 cc/g.** Typical compressed materials have pore volumes in this diameter range of more than about 0.02 cc/g. Pore volume, pore diameter and density may be determined using a Quantachrome Instruments PoreMaster 60 mercury intrusion porosimeter and associated computer software program known as "Porowin." The procedure is documented in the Quantachrome Instruments PoreMaster Operation Manual...

Applicants amend claim 8 and to use the language contained within the specification. Reconsideration and withdrawal of the rejection of claims 8 and 23 under 35 U.S.C. § 112,

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second paragraph, are respectfully requested.

#### **IV. Conclusion**

Early consideration and prompt allowance of the claims are respectfully requested. If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750/MCP5007USCIP1/LAD.

Respectfully submitted,

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